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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,900	02/12/2002	Isabelle Arnould-Reguigne	03806.0537	3572

7590 02/24/2004

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EXAMINER

KAPUST, RACHEL B

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/072,900	Applicant(s) ARNOULD-REGUIGNE ET AL.	
	Examiner Rachel B. Kapust	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 10-11, 14-15, 26-30, and 33-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12, 13, 16-25, 31, 32 and 40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of Group I (encompassing claims 1-9, 12-13, 16-25, 31-32, and 40 as drawn to SEQ ID NOS: 1 and 3) is acknowledged. The traversal is on the ground(s) that Applicants argue 1) SEQ ID NO: 1 encompasses SEQ ID NO: 2 and therefore a search of SEQ ID NOS: 1 and 3 would be coextensive with a search of SEQ ID NOS: 2 and 4; and 2) there is not a substantial burden on the Examiner because a search of Group I should encompass the search of the subject matter of Groups II and VI.

Applicant's arguments have been fully considered and have been found to be partially persuasive. SEQ ID NOS: 2 and 4 will be searched along with SEQ ID NOS: 1 and 3.

Regarding Applicant's argument that there is not a substantial burden on the Examiner to search the subject matter of Groups II and VI, different groups of nucleic acids, proteins, antibodies, and methods represent different inventions and require different, non-contiguous searches, as evidenced by their different classification. They require separate searches of separate databases. The search for methods of use is separate because it requires additional considerations as to the methodology itself. Thus to consider all of these groups would constitute an undue burden because each requires considerations that are separate from each of the others.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The requirement is still deemed proper and is therefore made FINAL. Claims 10, 11, 14, 15, 26-30, and 33-39 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.48(b). Claims 1-9, 12-13, 16-25, 31-32, and 40 as drawn to SEQ ID NOS: 1-4 are under consideration.

### ***Specification***

The following is a quotation of 37 CFR § 1.821 (d) which sets forth rules regarding applications containing sequence listings:

Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

On page 99 of the specification Applicants list the sequences of two multiple cloning sites (line 20 and lines 28-29). If these sequences are not in the sequence listing, the sequence listing would need to be amended to include the sequences, and the specification needs to be amended so that the sequences are preceded by their sequence identifiers.

On page 94 of the specification, line 14 reads "SEQ ID N° 1-4". It should read "SEQ ID NO: 1-4" or "SEQ ID NOS: 1-4". Appropriate correction is required.

The use of the trademarks VERAPAMIL™ (p. 91), SUPERSRIPT™ (p. 92), and ABI PRISM™ (p. 93) have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Claim Objections***

Claims 16 and 17 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

Claim 16 is objected to because of the following informalities: Claim 16(a) is drawn to what appears to be a Markush group. However, there is no "and" separating 16(a)(2) and 16(a)(3). Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 21, 22, 24, and 25 are rejected under 35 U.S.C. 101 because the claimed inventions are directed to non-statutory subject matter. Claims 21, 22, 24, and 25 are drawn to host cells comprising recombinant vectors. The claims read on cloned humans which are non-statutory subject matter. The rejection may be obviated by amending the claims to read “an isolated host cell” so long as there is support for the amendment in the specification.

Claims 1-9, 12, 13, 16-25, 31-32, and 40 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claims 1-9, 12, 13, 16-25, 31-32, and 40 are directed to nucleic acid molecules comprising any one of SEQ ID NOS: 1-4. The specification asserts that SEQ ID NOS: 1-4 are transcripts of a member of the ATP-binding protein cassette subfamily A (ABCA). More specifically, the specification discloses that SEQ ID NOS: 1-4 are ABCA12 transcripts comprising 7788, 7551, 7788, and 7551 nucleotides, respectively (p. 51). The claimed nucleic acid molecules are not supported by either a specific and substantial asserted utility or a well-established utility.

A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a “real world” use for the claimed invention. See *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966):

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

Uses such as screening for small molecules and compounds that are agonists or antagonists or ABCA12 proteins (p. 23), identifying polymorphisms of ABCA12 genes, producing recombinant ABCA12 proteins (p. 19), and detecting the presence of ABCA polypeptides in a sample (p. 20) are useful only in research to determine the function of the encoded protein itself. There is no “specific benefit in currently available form” to be derived from such studies. Applicants teach that ABCA12 transcripts match with various ESTs generated by skin/epithelial cell cDNA (p. 9, lines 5-10). However, tissue-specific expression is not specific to the claimed nucleic acid molecules. Tissue-specific expression does not depend on any specific characteristics of the ABCA12 transcripts. Similarly, even though applicants teach the ABCA12 gene is located in the 2q34 locus of human chromosome 2, chromosomal location does not depend on any specific characteristic of the ABCA12 gene. Applicants also teach the ABCA12 nucleic acid molecules may be used for the manufacture of medicaments for the prevention or treatment of subjects affected by a dysfunction of lipophilic substances transport or by a pathology located on the chromosome locus 2q34 such as lamellar ichthyosis, polymorphic congenital cataract or insulin-dependent diabetes mellitus (p. 65, lines 14-19). These diseases are not known to be associated with ABCA12 proteins; rather, the diseases are associated with a particular region on chromosome 2. The specification also discloses ABCA12 proteins can be used in the treatment of arteriosclerosis, inflammation, cardiovascular diseases, and metabolic diseases (p. 66, lines 8-12). Merely listing a number of possibilities is not sufficient to identify or confirm a “real world” context of use; clearly further research would be required to identify a disease in which the encoded protein is involved. Applicants have not stated that any diseases are known to be associated with ABCA12 proteins, and Applicants have not provided an activity for ABCA12 proteins. Thus, significant further research is required to identify a disease for which it could be used, or a disease for which its presence would be diagnostic. See *Brenner v. Manson*, noting that “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.” A patent is therefore not a license to experiment.

The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and credible utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. The specification asserts the

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polypeptides encoded by ABCA12 are likely to be involved in the transport of various substrates comprising sugars, metals, amino acids or vitamins, and they may function as chloride channels, bile salt transporters, glutathione conjugate transporters, HLA class I antigen transporters, sulfonylurea receptors, or lipidic derivative transporters (p. 9, lines 13-20). The specification fails to assert any activity for the encoded ABCA 12 polypeptide other than those generally recognized to be attributes of polypeptides of the ABCA superfamily. Identifying a nucleic acid molecule as encoding a polypeptide of this family does not endow the nucleic acid molecule with a specific and substantial utility. The ATP-binding cassette (ABC) transporter superfamily contains some of the most functionally diverse proteins known (see for example Dean *et al.* (1995), *Curr Opin Genet Dev* 5: 779-785 and Ames *et al.* (1992), *FASEB J.* 6(9): 2660-2666). Dean *et al.* teach that unlike ABC genes in bacteria, where the transport functions of the gene products have been well described, the homologous genes in higher eukaryotes are much less well studied because of the significantly higher complexity of eukaryotic systems and the apparent difference in function of even highly homologous genes (p. 779). Thus, simply knowing that a polypeptide is homologous to a member of the ABC superfamily does not impart a function on the polypeptide. The biophysical and pharmacological characteristics of the ABCA12 could not be discerned by simply identifying it as a member of the ABC superfamily. There is therefore no well-established utility for members of this family; utility is specific to the individual protein.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 12, 13, 16-25, 31-32, and 40 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.



Claims 2-5 are rejected under 35 U.S.C. 112, first paragraph because the specification, were it enabling for a nucleic acid molecule comprising any one of SEQ ID NOS: 1-4, would not reasonably provide enablement for polynucleotides that are 80%, 85%, 90%, 95% or 98% identical to SEQ ID NO: 1, 2, 3 or 4, polynucleotides that comprise at least 8 consecutive nucleotides of SEQ ID NO: 1, 2, 3 or 4, or polynucleotides that hybridize with a nucleotide sequence comprising SEQ ID NO: 1, 2, 3 or 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The problem of predicting polypeptide structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the polypeptide is extremely complex. While it is known that many amino acid substitutions are generally possible in any given polypeptide, the positions within the polypeptide's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the polypeptide's structure/function relationship, such as various sites or regions directly involved in binding, activity, and in providing the correct three-dimensional spatial orientation of binding and active sites. Particular regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions.

However, Applicants have provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the polypeptide that are tolerant to change and the nature and extent of changes that can be made in these positions. For instance, SEQ ID NOS: 1-4 comprise 7788, 7551, 7788, and 7551 nucleotides, respectively. Claims 2-4 are drawn to isolated nucleic acid molecules that are fragments of any one of SEQ ID NOS: 1-4 comprising at least 8 consecutive nucleotides of SEQ ID NO: 1, 2, 3 or 4 and nucleic acid molecules that are 80%, 85%, 90%, 95% or 98% identical to any one of SEQ ID NOS: 1-4. Claim 5 is drawn to a nucleic acid molecule that hybridizes with a nucleic acid comprising any one of SEQ ID NOS: 1-4. Sequences that hybridize to any one of SEQ ID NOS: 1-4 could be extremely different from SEQ ID NOS: 1-4. While the claims encompass hundreds of thousands of sequences, there are no

functional limitations for the sequences in the claims. The encoded polypeptides could have structures that are very different from that of SEQ ID NO: 5 or 6, and the functions could be very different from that of a polypeptide comprising SEQ ID NO: 5 or 6. Regarding the claimed nucleic acid molecules comprising fragments of at least 8 consecutive nucleotides of any one of SEQ ID NOS: 1-4, the specification provides no guidance as to which (if any) of the nucleotides can be changed or deleted to yield a functional equivalent of the polypeptide comprising SEQ ID NO: 5 or 6. More importantly, because there is no specific activity disclosed for the polypeptide comprising SEQ ID NO: 5 or 6, and there is no functional limitation in the claim, there would be no means for predicting or identifying other polypeptides that would have a similar activity. Even if an active site or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity.

Due to the large quantity of experimentation necessary to generate the infinite number of variants recited in the claims and screen the same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on polypeptide structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

In addition, claims 2-5 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are drawn to a genus, *i.e.* nucleic acid molecules encoding variants of SEQ ID NOS: 1-4. The genus includes isolated nucleic acid molecules that are fragments of SEQ ID NOS: 1-4, nucleic acid molecules that hybridize to any one of SEQ ID

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NOS: 1-4, and nucleic acid molecules that are 80%, 85%, 90%, 95% or 98% identical to any one of SEQ ID NOS: 1-4. Thus, because the claims have no functional limitations, the claims are drawn to a genus of nucleic acid molecules that is defined by sequence identity. Applicants have disclosed four species, nucleic acid molecules consisting of any one of SEQ ID NOS: 1-4, but have not disclosed sufficient species for the broad genus which includes isolated nucleic acid molecules that are fragments of SEQ ID NOS: 1-4, sequences that hybridize to SEQ ID NOS: 1-4, and nucleic acid molecules that are 80%, 85%, 90%, 95% or 98% identical to any one of SEQ ID NOS: 1-4.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. The instant disclosure of four species of nucleic acid molecules does not adequately describe the scope of the claimed genus, which encompasses hundreds of thousands of different nucleic acid molecules encoding polypeptides with varying structures and functions. The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of nucleic acid molecules. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. Structural features that could distinguish the compounds in the genus from other nucleic acid molecules encoding ABC polypeptides are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teaching sufficient to enable one of skill to isolate and identify the nucleic acid molecules encompassed: there is no guidance in the art as to what the defining characteristics of ABCA12 might be. Thus, no identifying characteristics or properties of the instant nucleic acid molecules are provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, the disclosure of SEQ ID NOS: 1-4 is insufficient to describe the genus. Therefore, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 13, 16-21, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-8, 13, 16-21, and 31 are drawn to sequences that are complementary to any one of SEQ ID NOS: 1-4. It is not clear whether the claims are meant to encompass only sequences that are complementary to the entire sequence comprising SEQ ID NO: 1, 2, 3, or 4, or whether the claims are meant to encompass sequences comprising regions that are complementary to any one of SEQ ID NOS: 1-4 and nucleic acid fragments that hybridize to any one of SEQ ID NOS: 1-4. One skilled in the art would not know what the metes and bounds of “complementary” are.

Claim 5 is drawn to a nucleic acid molecule that hybridizes to any one of SEQ ID NOS: 1-4 under high stringent conditions. The term “high stringent conditions” is a relative term which renders the claims indefinite. The term is not defined by the claim, and whereas the specification provides examples of high stringent conditions (p. 34), the specification neither provides a definition of high stringent conditions nor a standard for ascertaining the requisite degree, and one skilled in the art would not be reasonably apprised of the scope of the invention. It is unclear what amount hybridizing would occur under “high stringent” conditions. One skilled in the art would not know what the metes and bounds of high stringent conditions are.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 2, 5, 7, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Mahairas *et al.*, GenBank Acc. No. AQ743553. Claim 2 is drawn to isolated nucleic acids comprising at least 8 consecutive nucleotides of any one of SEQ ID NOS: 1-4. Mahairas *et al.* teach a sequence that is 100% identical to SEQ ID NOS: 1-4 over a span of 153 bases (see enclosed alignment of AQ743553 with SEQ ID NOS: 1 and 3). Claim 5 is drawn to isolated nucleic acid molecules that hybridize under high stringency with a nucleic acid comprising any one of SEQ ID NOS: 1-4 or a complementary sequence thereof. Due to the homology over the aforementioned 153 base region, a person of ordinary skill in the art would expect that under high stringency conditions the sequence taught by Mahairas *et al.* would hybridize with a sequence complementary to either SEQ ID NO: 1 or 2. Claim 7 is drawn to a nucleotide probe comprising at least 15 consecutive nucleotides of SEQ ID NO: 1 or 3. Claim 16 is drawn to a kit for detecting a nucleic acid sequence wherein the kit comprises a nucleotide probe comprising at least 15 consecutive nucleotides of any one of SEQ ID NOS: 1-4. A kit is merely an intended use, and as stated previously Mahairas *et al.* teach a sequence that is 100% identical to SEQ ID NOS: 1-4 over a span of 153 bases. Thus, the sequence as taught by Mahairas *et al.* anticipates claims 2, 5, 7, and 16.

***Conclusion***


NO CLAIMS ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel B. Kapust whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RBK  
2/19/04

  
JANET ANDRES  
PATENT EXAMINER